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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,222	09/08/2003	Morton M. Mower	302527US78	1067

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

NOTIFICATION DATE	DELIVERY MODE
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01/12/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/656,222	Applicant(s) MOWER, MORTON M.	
	Examiner MICHAEL KAHELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,20,27,28,34,67 and 69-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,20,27,28,34,67 and 69-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

- 1.** The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2.** Claims 1, 20, 27, 28, 34, 67, and 69-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The "Remarks" of 5/18/2010 and the declaration of 1/21/2010 indicate that delivering stimulation to "only a left ventricle" requires a particular placement and/or type of septal electrode. The specific type of electrode and method of installing the electrode appears to be described in U.S. Patent No. 5,728,140 to Salo (see par. 058 of Applicant's disclosure). However, the examiner was unable to locate an adequate incorporation by reference of this document. See 37 C.F.R. 1.57(b)(1). Since the subject matter of this insulated/uninsulated configuration is "essential subject matter" needed to provide written description for the claims, and has not been properly incorporated, the disclosure is lacking written description of an electrode that is implanted in the right septal wall and stimulates only the left ventricle.
- 3.** Claims 1, 20, 27, 28, 34, 67, and 69-71 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Elements and steps critical

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or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The "Remarks" of 5/18/2010 and the declaration of 1/21/2010 indicate that delivering stimulation to "only a left ventricle" requires a particular placement of the septal electrode. The disclosure does not indicate where this particular location is or how to determine the location, but does indicate that the type of electrode and method of installing the electrode is disclosed in U.S. Patent No. 5,728,140 to Salo. It would appear that delivering stimulation to "only a left ventricle" requires the insulated/uninsulated configuration shown in, *e.g.*, Figure 2 of Salo and described at the top of column 2. However, the examiner was unable to locate an adequate incorporation by reference of this document. See 37 C.F.R. 1.57(b)(1). Since the subject matter of this insulated/uninsulated configuration is "essential subject matter" needed to provide enablement for the claims, and has not been properly incorporated, the disclosure is not enabling.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3, 20, 27, 28, 34, 67, and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 2003/0105496, hereinafter "Yu") in view of Salo (US 5,728,140, hereinafter "Salo").

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6. In regards to claims 1, 27, 34, 67, and 71, Yu discloses providing a first electrode to the left ventricle coronary vein, a second electrode to the septum, and performing intrachamber resynchronization with the electrodes (pars. 0013, 0027 and 0035). Yu does not explicitly disclose that the septal electrode 144 delivers stimulation to only the left ventricle. However, Salo teaches a septal helical electrode that delivers stimulation to only the left ventricle (col. 1, line 67 to col. 2, line 3) to provide the predictable result of reaching the desired chamber for pacing therapy without the accompanying thrombosis complications. Therefore, it would have been obvious to one having ordinary skill in the art to provide Yu's invention with a septal electrode provides stimulation to only the left ventricle to provide the predictable result of reaching the desired chamber for pacing therapy without the accompanying thrombosis complications.

7. In regards to claims 3 and 69, Yu discloses receiving signals from multiple left ventricular sites (par. 0028).

8. In regards to claims 20 and 70, the electrodes are endocardial electrodes (Fig. 3).

9. In regards to claim 28, delivering includes providing a lead through the SVC, RA, ostium of the coronary sinus, and coronary vein (par. 0027 and Fig. 3).

Response to Arguments

10. Applicant's arguments filed 11/17/2010 have been fully considered but they are not persuasive. In regards to the written description rejection under §112, paragraph 1, Applicant argued that an analysis of the level of ordinary skill in the art is required to

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support a *prima facie* case and lacking in the previous Office Action. The examiner respectfully disagrees that such a showing is indispensably required to support a written description rejection, but instead serves as a useful guidepost to determine the ultimate question of whether applicant shows possession of the scope of the invention now claimed and whether the omitted subject matter is critical for an artisan of ordinary skill to determine possession. None of the authority cited by Applicant uses mandatory language for this determination. Furthermore, the examiner respectfully notes that (for at least the limitations drawn to stimulating only the left ventricle from a right ventricular approach) this determination of the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement has been stipulated by Applicant at item 13 of Exhibit A of 1/21/2010. Here, Applicant declared that the particular placement location of the electrode to provide this effect “has never been widely appreciated” and critical to the practice of the invention, but silent in the prior art applied to the claims at the time. It appears that Applicant’s position is that this specific placement location is beyond the ordinary level of skill and knowledge in the art for purposes of avoiding the prior art, but is included within the ordinary level of skill and knowledge for purposes of sufficiency of disclosure. The examiner respectfully disagrees that this specific placement and partially insulated/uninsulated electrode configuration (as shown by Salo) is within the ordinary level of skill in the art due to the compelling statement made by Applicant concerning the difficulties of pacing only the left ventricle, the solution to which is not widely appreciated.

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11. The above rejections under §112 rest on the notion that this electrode placement location and electrode configuration (as shown in, *e.g.*, Salo at Figure 2) are critical to the independent requirements of adequately describing the invention and enabling the invention's practice (specifically delivering stimulation to "only a left ventricle" from a right ventricular approach). Applicant does make note of Salo in paragraph 058 of the disclosure, but without an adequate incorporation by reference, the examiner is unfortunately precluded from considering Salo as part of the original disclosure to provide this critical information. This and the other excerpts cited by Applicant in "Remarks" do disclose pacing only in the left ventricle and using a helical screw-type electrode in various portions of the septum, but Exhibit A of 1/21/2010 indicates that this is not enough -- a specific type of electrode and placement location are necessary to achieve this effect, these specifics have never been widely appreciated, and these specifics do not draw description or enablement from the original disclosure.

12. In regards to the art rejections, Applicant argued that Yu and Salo represent divergent teachings because Yu does not disclose stimulating only a left ventricle, but instead teaches stimulating both ventricles. However, the claims do not require the absence of stimulation to other areas of the heart, but only positioning electrodes to deliver stimulation to only a left ventricle. In other words, the claims permit an electrode configuration that delivers stimulation to only a left ventricle and another electrode configuration that delivers stimulation to other areas as long as at least one configuration delivers stimulation to only a left ventricle. The examiner respectfully maintains that modifying Yu's stimulation electrode 144 with Salo's electrode

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configuration shown in, *e.g.*, Fig. 4 would have been *prima facie* obvious to provide the predictable result of reaching the desired chamber for pacing therapy without the accompanying thrombosis complications. This is a simple substitution of one known electrode configuration for another to yield no more than predictable results, and the examiner's position is that this substitution would have been well within the ordinary level of skill and knowledge in the art at the time of invention.

Conclusion

13. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHRELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Primary Examiner, Art Unit 3762